

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/403,437	ODIDI ET AL.	
	Examiner Retford Berko	Art Unit 1615	

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to 11/2/04.
2.  The allowed claim(s) is/are 1-3 and 5-35.
3.  The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All      b)  Some\*    c)  None    of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
7.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application (PTO-152)
6.  Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_

*James M. Spear*  
JAMES M. SPEAR  
PRIMARY EXAMINER  
AU 1615

## **DETAILED ACTION**

**Acknowledgement:** The Amendment filed November 2, 2004 is acknowledged.

1. Claims 1-3 and 5-35 are pending.
2. Claim 4 was cancelled in view of applicant's amendment.

The following claims are allowed: Claims 1-3 and 5-35, following the amendment that stipulates the specific nature of the first polymer in the composition as EC—this amendment will be applicable to all independent claims.

3. The following is an examiner's reasons for allowance:

The instant claims are directed toward a controlled release composition comprising an active agent incorporated within polymers: a first polymer (ethyl cellulose; EC) and a second polymer component (a mixture of hydroxyethyl cellulose, HEC and hydroxypropyl methyl cellulose, HPMC); wherein the first and second polymers have different wettability characteristics. The claims are also directed toward a method of making the controlled release composition having the active agent, first polymer (ethyl cellulose) and second polymer. Applicant submitted a first 37 CFR 1.132 Declaration filed August 21, 2002 and a second 1.132 Declaration setting forth unexpected results to show non-equivalence of polymers and combinations thereof by applicant distinguishing instant claims from the prior art disclosures.

4. The claims are distinguished from the closest prior art of record (Sangekar et al (US 5, 000, 962); Stupak et al (US 5, 162, 117) and Zhans et al (US 6, 083, 532) because:
  - (a) applicant obtains differential controlled release of drug by using a specific combination of polymers—a first polymer (ethyl cellulose; EC) and a second polymer component (a mixture of hydroxyethyl cellulose, HEC and hydroxypropyl methyl cellulose, HPMC); as

distinguished from the instant claims, the prior art does not specify the use of the specific combination of polymers for the controlled release of drug

- (b) applicant demonstrated unexpected results--evidenced by non-equivalence of polymers combinations (HPMC, HEC and EC) that yield different rates of release of drug, distinguishing the instant claims from the prior art disclosure that does not show differential release of drug from release.
- (c) according to applicant, the differential release of drug from the polymer combinations constitutes an improvement over the prior art in the delayed dosing of drug that is not disclosed in the prior art which unlike the instant claims does not show differences in drug release profiles using the same combination of polymers as claimed by applicant.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee.

Such submission should be clearly labeled "Comments on Statement of Reasons for Allowance".

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is 571-272-0590. The

*Bob*

examiner can normally be reached on M-F from 8.00 am to 5.30 pm

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Thurman K Page**, can be reached on 571-272-0602.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rob  
12/6/64

*James M. Spear*

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